UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LIQUIDIA TECHNOLOGIES, INC., *Plaintiff*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *Defendants*.	Case No. 1:24-cv-02428-JDB

DECLARATION OF MIKE KASETA IN SUPPORT OF PLAINTIFF LIQUIDIA TECHNOLOGIES, INC.'S MOTION FOR A PRELIMINARY INJUNCTION

I, Mike Kaseta, declare and state as follows:

1. I am the Chief Operating Officer ("COO") and Chief Financial Officer ("CFO") of Liquidia Corporation and Liquidia Technologies, Inc. (collectively, "Liquidia"). I have served as CFO since December 2020 when I joined Liquidia, and as COO since January 2024. I have an extensive background in corporate finance, business strategy, and commercialization of biopharmaceutical products in large pharmaceutical companies and small biotech companies.

2. I submit this declaration in support of Liquidia's motion for preliminary injunction to enjoin the August 16, 2024 decision by Defendant United States Food and Drug Administration ("FDA") to award three-year new clinical investigation exclusivity ("NCI exclusivity") to Tyvaso DPI (the "Exclusivity Decision"), a drug sold by United Therapeutics Corporation ("UTC"). This declaration is based on my understanding of information available to me at this time.

3. Liquidia is a late-stage clinical biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, including treatment of rare cardiopulmonary diseases such as pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD").

4. Liquidia is incorporated in Delaware (as of June 2020) and is headquartered in North Carolina. As of August 27, 2024, Liquidia employed 154 salaried and 11 hourly employees.

5. Since its inception, Liquidia has invested heavily in the development of its product candidates and technologies, as well as in recruiting management and scientific personnel. Liquidia has not commenced the commercialization of any of its product candidates and all of its limited revenue to date has come from licensing and collaboration arrangements.

6. Liquidia's first drug product candidate is Yutrepia, an inhaled dry powder treprostinil formulation that safely and effectively treats patients with PAH and PH-ILD. Since at least 2012, Liquidia has invested substantial time and money in formulating Yutrepia as well as conducting clinical investigations for Yutrepia.

7. Yutrepia would compete with treprostinil drugs sold by UTC, a company that has held a decades-long monopoly over treprostinil products through four drugs, including Remodulin, Orenitram, Tyvaso Inhalation Solution, and Tyvaso DPI. UTC's longstanding monopoly has limited treatment options available to patients with PAH and PH-ILD and prevents price competition for treprostinil drug treatments. FDA's Exclusivity Decision reinforces UTC's longstanding monopoly, and prevents patients from having access to Yutrepia's safe and effective treatment of PAH and PH-ILD.

8. The Exclusivity Decision causes ongoing substantial harm to Liquidia by blocking full approval for Yutrepia until at least May 23, 2025, and threatens Liquidia in numerous ways.

9. First, the Exclusivity Decision deprives Liquidia of the opportunity to market and distribute Yutrepia for at least nine months. That is a substantial period of time to market Yutrepia for sale in the United States as a treatment option for PAH and PH-ILD patients, and it is time that Liquidia can never get back if the Exclusivity Decision stands.

10. Had FDA granted full approval to distribute Yutrepia effective August 16, 2024, Liquidia was ready to launch Yutrepia by early September 2024. Liquidia expected to compete vigorously to break UTC's decades-long monopoly and empower patients nationwide with greater choice. It is my understanding that the estimated market opportunity for inhaled treprostinil is currently at a $1.5 billion run rate, with the potential to grow to more than $3 billion in the coming years. By depriving Liquidia of the opportunity to distribute Yutrepia, the Exclusivity Decision prevents Liquidia from realizing any economic gain from Yutrepia sales for at least three quarters.

11. Second, by refusing to give full approval to Yutrepia, FDA's Exclusivity Decision negatively impacts Liquidia's salesforce and revenue. Liquidia employs a targeted sales force that was prepared—upon full approval for Yutrepia—to communicate with physicians and hospital pharmacies involved in the treatment of PAH and PH-ILD in the United States, as well as other stakeholders involved in the distribution and reimbursement of medicines to treat patients. In fact, Liquidia expanded its sales force in the fourth quarter of 2023 in anticipation of FDA approval for Yutrepia following the March 31, 2024 expiration of an exclusivity period for UTC's Tyvaso. The Exclusivity Decision deprives Liquidia's sales force of the ability to carry out their job duties and responsibilities to promote Yutrepia and generate corresponding revenue for at least nine months. As a result of the Exclusivity Decision and the sales force's inability to generate sales commissions, Liquidia may be unable to retain its sales force.

12. Third, by depriving Liquidia of the opportunity to market Yutrepia immediately, the Exclusivity Decision also threatens Liquidia's financial health. In recent years, Liquidia has incurred significant operating losses. Liquidia's net loss was $68.9 million for the six months ended June 30, 2024 and $78.5 million and $41 million for the years ended December 31, 2023 and 2022, respectively. As of June 30, 2024, Liquidia had an accumulated deficit of $498 million. Furthermore, in anticipation of the potential commercialization of Yutrepia, Liquidia's operating losses have increased. For example, as it prepared for a potential launch, Liquidia incurred general and administrative expenses of $19.9 million for the three months ended June 30, 2024, compared to $9.2 million for the three months ended June 30, 2023. The increase of $10.7 million or 116% was primarily due to a $6.3 million increase in personnel expenses (including stock-based compensation) driven by higher headcount and expansion of Liquidia's sales force in the fourth quarter of 2023, a $2.2 million increase in commercial and consulting expenses. Without the ability to immediately market Yutrepia, Liquidia is deprived of revenue streams it had anticipated from a full launch of Yutrepia and that it would have used to address these operating losses.

13. Fourth, by depriving Liquidia of the opportunity to market Yutrepia immediately, the Exclusivity Decision also threatens to harm Liquidia's ability to invest in ongoing development efforts for its pipeline drug candidates and products.

14. Liquidia's future funding requirements are heavily determined by the timing of the potential commercialization of Yutrepia, the indications for which Yutrepia is approved, and the resources needed to support the development of Liquidia's other product candidates. If Liquidia cannot obtain necessary funding due to delayed approval of Yutrepia, Liquidia could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect Liquidia's business prospects.

Liquidia may not be able to complete the development and commercialization of these new clinical development programs.

15. In short, FDA's Exclusivity Decision substantially harms Liquidia and threatens further harms to Liquidia. Full approval of Yutrepia effective immediately for any of its intended uses would prevent these harms.

16. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 27th day of August 2024.

Mike Kaseta
Chief Operating Officer and Chief Financial Officer for Liquidia Corporation and Liquidia Technologies, Inc.